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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/814,527	
	Filing Date	March 30, 2004	
	First Named Inventor	Robert Alpern	
	Art Unit	1615	
	Examiner Name	Thurman K. Page	
Total Number of Pages in This Submission		Attorney Docket Number	29329-714.201

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO/SB/08 Return Post Card 32 References <i>International Search Report</i>
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT			
Firm Name	WILSON SONS NIDGOODRICH & ROSATI		
Signature	<i>Anie K. Roche</i>		
Printed Name	Anie K. Roche		
Date	October 21, 2005	Reg. No.	50,512

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail (EV 711413126 US) in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature	<i>Abigail Cruz</i>		
Typed or printed name	Abigail Cruz	Date	10/21/05

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket No. 29329-714.201
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Robert Alpern, et al.

Serial Number: 10/814,527

Filing Date: March 30, 2004

Title: METHODS AND COMPOSITIONS FOR
TREATMENT OF ION IMBALANCES

Group Art Unit: 1615

Examiner: Thurman K. Page

CONFIRMATION NO: 6886

EXPRESS MAIL LABEL NO.: EV 711413126 US

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

Sir:

Applicant(s) hereby submit(s) an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicant(s) respectfully request(s) that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant(s) further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.
-- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).
-- AND/OR --
- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, of a portion (i.e. English language abstract), of the non-English language reference(s) is provided herewith
- ☒ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29329-714.201).

Respectfully submitted,


WILSON SONSINI GOODRICH & ROSATI

Dated: _____

10/21/2005

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

By: _____


Anne K. Roche, Reg. No. 50,512



CERTIFICATION

(Attachment to Information Disclosure Statement)

- ☒ 37 C.F.R. §1.97(e)(1). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ 37 C.F.R. §1.97(e)(2). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Respectfully submitted,

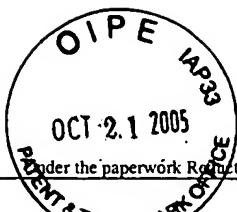
Dated: _____

10/21/2005

By: _____

Anie K. Roche
Reg. No. 50,512

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(650) 565-3856
Customer No. 021971



Substitute for Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/814,527
				Filing Date	March 30, 2004
				First Named Inventor	Robert Alpern
				Art Unit	1615
Examiner Name	Thurman K. Page				
Sheet	1	of	3	Attorney Docket Number	29329-714.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-2,611,730	09-23-1952	Heming et al.	
	2.	US-2,909,462	10-20-1959	Warfield et al.	
	3.	US-4,143,130	03-06-1979	Imondi	
	4.	US-4,470,975	09-11-1984	Berger	
	5.	US-5,051,253	09-24-1991	Llyod-Jones	
	6.	US-5,141,927	08-25-1992	Krotkiewski	
	7.	US-5,281,631	01-25-1994	Horwitz	
	8.	US-5,374,422	12-20-1994	Pierre	
	9.	US-5,607,669	03-04-1997	Mandeville	
	10.	US-5,633,344	05-27-1997	Figuly	
	11.	US-5,718,920	02-17-1998	Notenbomer	
	12.	US-6,294,163	09-25-2001	Dhal	
	13.	US-2002/0146386 A1	10-10-2002	Simon et al.	
	14.	US-2003/0027789 A1	02-06-2003	Yamaoka et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	15.	EP 0730494 B1	02-04-1998	Salternate B.V.		
	16.	WO 01/51063 A1 (with English abstract)	07-19-2001	Otsuka Pharmaceutical Factory, Inc.		
	17.	WO 02/062356 A2	08-15-2002	Ash Medical Systems, Inc.		
	18.	WO 02/40039 A2	05-23-2002	The Dow Chemical Company		
	19.	WO 92/10522	06-25-1992	Imperial Chemical Industries PLC		
	20.	WO 94/27619	12-08-1994	Geltex, Inc.		
	21.	WO 95/14531	06-01-1995	Sansel		

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/814,527
				Filing Date	March 30, 2004
				First Named Inventor	Robert Alpern
				Art Unit	1615
				Examiner Name	Thurman K. Page
Sheet	2	of	3	Attorney Docket Number	29329-714.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	22.	Berlyne, G.M., et al. "Cation exchange resins in hyperkalaemic renal failure." (1967) Israel J Med Sci 3(1): 45-52	
	23.	Chourasia, M.K., et al., "Pharmaceutical approaches to colon targeted drug delivery systems." (2003) J. Pharm Pharm Sci 6(1): 33-66.	
	24.	Corcoran, A.C., et al., "Controlled observations on the effect of low sodium dietotherapy in essential hypertension." (1951) Circulation 3(1): 1-16.	
	25.	Danowski, T.S., et al., "Changes in fecal and serum constituents during ingestion of cation and anion exchangers." (1953) Ann N Y Acad Sci. 57(3): 273-9	
	26.	Emerson, K., Jr., et al., "The role of the gastro-intestinal tract in the adaptation of the body to the prevention of sodium depletion by cation exchange resins." (1953) Ann N Y Acad Sci. 57(3): 280-90	
	27.	Emmett, M., et al. "Effect of Three Laxatives and a Cation Exchange Resin on Fecal Sodium and Potassium Excretion." (1995) Gastroenterology 108(3): 752-60	
	28.	Evans, B.M., et al. "Ion-exchange resins in the treatment of anuria." (1953) Lancet 265(6790): 791-5	
	29.	Field, H., Jr., et al., "Electrolyte changes in ileal contents and in feces during restriction of dietary sodium with and without the administration of cation-exchange resin." (1955) Circulation 12(4): 625-9	
	30.	Field, H., Jr., et al., "Mechanisms regulating the retention of sodium in the feces by cation-exchange resin: release of base from the resin by bacterial fermentation in the terminal ileum." (1958) J Lab Clin Med 51(2): 178-84	
	31.	Fourman, P. "Capacity of a cationic exchange resin (zeo-karb 225) in vivo." (1953) British Medical Journal 1(4809): 544-6	
	32.	Greenman, L., et al. "Biochemical changes accompanying the ingestion of a carboxylic cation exchanger in the hydrogen, ammonium, sodium, potassium, or calcium form." (1951) J Clin Invest. 30(9): 995-1008	
	33.	Gruy-Kapral, C., et al., "Effect of single dose resin-cathartic therapy on serum potassium concentration in patients with end-stage renal disease." (1998) J Am Soc Nephrol 9(10): 1924-30	
	34.	Harthon, J.G.L., et al., "A CASE OF UREMIA AND HYPERPOTASSEMIA TREATED WITH SULPHONIC CATION-EXCHANGE RESIN" (1952) Acta Med Scan., 144(3): 230-6	

Examiner signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Sheet	3	of	3	Attorney Docket Number	29329-714.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	35.	Heming A. E., et al., "Considerations in the selection of cation exchange resins for therapeutic use." (1953) Ann N Y Acad Sci. 57(3):239-51	
	36.	Irwin, L., et al. "The effect of a cation exchange resin on electrolyte balance and its use in edematous states." (1949) J Clin Invest. 28(6, Pt. 2): 1403-11	
	37.	Kohlstaedt, K.G., et al., "Clinical experience with mixtures of anion and cation exchange resins." (1953) Ann N Y Acad Sci. 57(3): 260-72	
	38.	Mason N.S., et al., "A new ion exchanger with high in vivo sodium capacity." (1985) Kidney Int Suppl. 28(17): S178-182	
	39.	Mateer, F.M., et al., "SODIUM RESTRICTION AND CATION EXCHANGE RESIN THERAPY IN NEPHROTIC CHILDREN" (1951) J Clin Invest. 30(9): 1018-26	
	40.	McChesney, E.W. "Effects of long-term feeding of sulfonic ion exchange resin on the growth and mineral metabolism of rats." (1954) Am J Physiol. 177(3):395-400	
	41.	McChesney, E.W., et al., "Some aspects of cation exchange resins as therapeutic agents for sodium removal." (1953) Ann N Y Acad Sci. 57(3):252-9	
	42.	Moustafine R.I., et al., "Characteristics of interpolyelectrolyte complexes of Eudragit E 100 with sodium alginate." (2005) Int J Pharm 294(1-2): 113-20	
	43.	Root, M.A., "Comparison of the in vivo sodium-removing activity of various types of ion exchange resins in rats." (1953) J Lab Clin Med 42(3): 430-7	
	44.	Ross, E.J., et al. "Observations on cation exchange resins in the small and large intestines." (1954) Clin Sci 13(4): 555-66	
	45.	Tust, R. H., et al., "THE EFFECTS OF MALETHAMER ON THE EXCRETION AND PLASMA LEVELS OF SODIUM, POTASSIUM, AND CHLORIDE (34990)" (1970) Proc Soc Exp Biol Med. 135(1): 72-6	
	46.	Wrong, O., et al., "The electrolyte content faeces." (1965) Proc R. Soc Med 58(12): 1007-9	

Examiner signature	Date Considered
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